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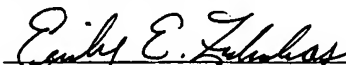
DOCKET NO.: C1037.70042US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Krieg et al.  
Serial No.: 10/613,524  
Confirmation No.: 4728  
Filed: July 3, 2003  
For: NUCLEIC ACID COMPOSITIONS FOR STIMULATING IMMUNE RESPONSES  
Examiner: Oluwatosin A. Ogunbiyi  
Art Unit: 1645

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 5<sup>th</sup> day of December, 2006.

  
Emily E. Zakauskas

MAIL STOP AMENDMENT

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,

By:



Maria A. Trevisan, Reg. No.: 48,207  
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600 Atlantic Avenue  
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Telephone: (617) 646-8000

Docket No.: C1037.70042US00  
Date: December 5, 2006  
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DOCKET NO.: C1037.70042US00

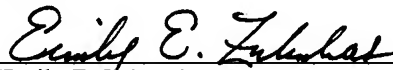
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Emily E. Zukauskas

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**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**PART I: Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed before the mailing of a first Office action on the merits in the above-identified case.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified PTO/SB/08). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>	<u>Docket No.</u>
10/532,746	09-09-2005	Ahluwalia et al.	*C1037.70035US01
11/179,008	07-08-2005	Hartmann et al.	*C1039.70044US02
11/411,975	04-26-2006	Uhlmann et al.	*C1041.70045US01
11/503,377	08-11-2006	Krieg et al.	*C1039.70061US01
11/503,483	08-11-2006	Krieg et al.	*C1039.70048US22
11/507,079	08-18-2006	Krieg et al.	*C1039.70035US04
11/526,197	09-22-2006	Krieg et al.	*C1039.70048US23
11/526,896	09-22-2006	Bratzler et al.	*C1037.70013US03
11/542,845	10-04-2006	Krieg et al.	*C1037.70048US01
11/543,314	10-04-2006	Lipford et al.	*C1041.70036US02
11/595,823	11-10-2006	Wagner et al.	*C1041.70035US01
11/598,207	11-10-2006	Krieg et al.	*C1039.70048US24

\*A copy of this reference is not provided as the Office has waived the requirement under 37 C.F.R. 1.98(a)(2)(iii) for submitting a copy of a cited U.S. patent application if it is scanned to the Image File Wrapper system and is available on Private PAIR.

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;

2. The enclosed form PTO-1449 (modified PTO/SB/08) be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.


By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.

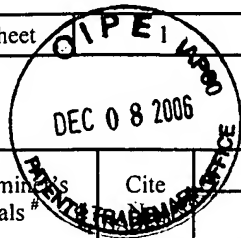
An early and favorable action is hereby requested.

Respectfully submitted,

By:   
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Maria A. Trevisan, Reg. No. 48,207  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
Telephone: (617) 646-8000

Docket No.: C1037.70042US00  
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FORM PTO-1449/A and B (modified PTO/SB/08)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	APPLICATION NO.: 10/613,524		ATTY. DOCKET NO.: C1037.70042US00	
	FILING DATE: July 3, 2003		CONFIRMATION NO.: 4728	
	APPLICANT: Krieg et al.			
	GROUP ART UNIT: 1645		EXAMINER: Oluwatosin A. Ogunbiyi	
Sheet	1	of	9	



### U.S. PATENT DOCUMENTS

Examiner's Initials	Cite	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A61	6,030,955		Stein et al.	02-29-2000
	A62	6,221,882		Macfarlane	04-24-2001
	A63	6,339,630		Macfarlane	06-04-2002
	A64	6,479,504		Macfarlane et al.	11-12-2002
	A65	6,521,637		Macfarlane	02-18-2003
	A66	6,558,670	B1	Friede et al.	05-06-2003
	A67	6,610,661	B1	Carson et al.	08-26-2003
	A68	6,821,957	B1	Krieg et al.	11-23-2004
	A69	6,943,240		Bauer et al.	09-13-2005
	A70	6,949,520		Hartmann et al.	09-27-2005
	A71	7,001,890		Wagner et al.	02-26-2006
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	A73	2003-0232856	A1	Macfarlane	12-18-2003
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	A76	2004-0053880	A1	Krieg	03-18-2004
	A77	2004-0067902	A9	Bratzler et al.	04-08-2004
	A78	2004-0076905	A1	Yagihashi et al.	04-22-2004
	A79	2004-0198680	A1	Krieg	10-07-2004
	A80	2004-0229835	A1	Krieg et al.	11-18-2004
	A81	2004-0234512	A1	Wagner et al.	11-25-2004
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	A83	2004-0235770	A1	Davis et al.	11-25-2004
	A84	2004-0235774	A1	Bratzler et al.	11-25-2004
	A85	2004-0235777	A1	Wagner et al.	11-25-2004
	A86	2004-0235778	A1	Wagner et al.	11-25-2004
	A87	2004-0247662	A1	Dow et al.	12-09-2004
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	A91	2005-0004144	A1	Carson et al.	01-06-2005
	A92	2005-0009774	A1	Krieg et al.	01-13-2005

EXAMINER:	DATE CONSIDERED:
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				APPLICANT: Krieg et al.			
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	A93	2005-0013812	A1	Dow et al.	01-20-2005
	A94	2005-0019340	A1	Garcon et al.	01-27-2005
	A95	2005-0031638	A1	Dalemans et al.	02-10-2005
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	A125	2005-0233995	A1	Krieg et al.	10-20-2005
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	A127	2005-0239732	A1	Krieg et al.	10-27-2005
	A128	2005-0239733	A1	Jurk et al.	10-27-2005

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	A129	2005-0239734	A1	Uhlmann et al.	10-27-2005
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	A131	2005-0245477	A1	Krieg et al.	11-03-2005
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	A135	2005-0256073	A1	Lipford et al.	11-17-2005
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	A141	2006-0003962	A1	Ahluwalia et al.	01-05-2006
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	A148	2006-0154890	A1	Bratzler et al.	07-13-2006
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	A152	2006-0211644	A1	Krieg et al.	09-21-2006
	A153	2006-0229271	A1	Krieg et al.	10-12-2006
	A154	2006-0241076	A1	Uhlmann et al.	10-26-2006
	A155	2006-0246035	A1	Ahluwalia et al.	11-02-2006

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
	B6	EP	0 302 758	A1	New England Medical Center Hospitals, Inc.	02-08-1989	
	B7	EP	0 468 520	A2	Mitsui Toatsu Chemicals, Inc.	01-29-1992	
	B8	WO	96/02555	A1	University of Iowa Research Foundation	02-01-1996	

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	B9	WO	99/56755	A1	University of Iowa Research Foundation	11-11-1999	
	B10	WO	00/06588	A1	University of Iowa Research Foundation	02-10-2000	
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	B12	WO	00/54803	A2	Panacea Pharmaceuticals, LLC.	09-21-2000	
	B13	WO	00/61151	A2	The Government of the United States of America	10-19-2000	
	B14	WO	01/22972	A2	Coley Pharmaceuticals, GmbH	04-05-2001	
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	B16	WO	01/45750	A1	Regents of the University of California	06-28-2001	
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	B18	WO	2004/007743	A2	Coley Pharmaceutical GmbH	01-22-2004	
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	B20	WO	2004/094671	A2	Coley Pharmaceutical GmbH	11-04-2004	
	B21	WO	2005/004910	A2	Intercell Ag	01-20-2005	
	B22	WO	2005/023289	A1	Intellectual Property Consulting Incorporated	03-17-2005	Abstract

#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C1	AGRAWAL et al., Medicinal chemistry and therapeutic potential of CpG DNA. Trends Mol Med. 2002 Mar;8(3):114-21.	
	C2	ASKEW et al., CpG DNA induces maturation of dendritic cells with distinct effects on nascent and recycling MHC-II antigen-processing mechanisms. J Immunol. 2000 Dec 15;165(12):6889-95.	
	C3	AUF et al., Implication of macrophages in tumor rejection induced by CpG-oligodeoxynucleotides without antigen. Clin Cancer Res. 2001 Nov;7(11):3540-3.	
	C4	BALLAS et al., Divergent therapeutic and immunologic effects of oligodeoxynucleotides with distinct CpG motifs. J Immunol. 2001 Nov 1;167(9):4878-86.	
	C5	BARAL et al., Immunostimulatory CpG oligonucleotides enhance the immune response of anti-idiotypic vaccine that mimics carcinoembryonic antigen. Cancer Immunol Immunother. 2003 May;52(5):317-27.	
	C6	BITTON et al., Cancer vaccines: a critical review on clinical impact. Curr Opin Mol Ther. 2004 Feb;6(1):17-26. Abstract Only.	
	C7	BLAZAR et al., Synthetic unmethylated cytosine-phosphate-guanosine oligodeoxynucleotides are potent stimulators of antileukemia responses in naive and bone marrow transplant recipients. Blood. 2001 Aug 15;98(4):1217-25.	
	C8	BROIDE et al., DNA-Based immunization for asthma. Int Arch Allergy Immunol. 1999 Feb-Apr;118(2-4):453-6.	

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Sheet	5	of	9		

C9	BRUNNER et al., Enhanced dendritic cell maturation by TNF-alpha or cytidine-phosphate-guanosine DNA drives T cell activation in vitro and therapeutic anti-tumor immune responses in vivo. J Immunol. 2000 Dec 1;165(11):6278-86.
C10	CARPENTIER et al., Successful treatment of intracranial gliomas in rat by oligodeoxynucleotides containing CpG motifs. Clin Cancer Res. 2000 Jun;6(6):2469-73.
C11	CARPENTIER et al., Oligodeoxynucleotides containing CpG motifs can induce rejection of a neuroblastoma in mice. Cancer Res. 1999 Nov 1;59(21):5429-32.
C12	CHAN et al., CpG-A and CpG-B oligodeoxynucleotides differentially affect the cytokine profile, chemokine receptor expression and T-cell priming function of human plasmacytoid dendritic cells. Blood. 2002;100:50b. Abstract #3666.
C13	CHATTERJEE et al., Idiotypic antibody immunotherapy of cancer. Cancer Immunol Immunother. 1994 Feb;38(2):75-82.
C14	CHOI et al., The level of protection against rotavirus shedding in mice following immunization with a chimeric VP6 protein is dependent on the route and the coadministered adjuvant. Vaccine. 2002 Mar 15;20(13-14):1733-40.
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C16	COOPER et al., Safety and immunogenicity of CPG 7909 injection as an adjuvant to Fluorix influenza vaccine. Vaccine. 2004 Aug 13;22(23-24):3136-43.
C17	DAFTARIAN et al., Two distinct pathways of immuno-modulation improve potency of p53 immunization in rejecting established tumors. Cancer Res. 2004 Aug 1;64(15):5407-14.
C18	DAVILA et al., Generation of antitumor immunity by cytotoxic T lymphocyte epitope peptide vaccination, CpG-oligodeoxynucleotide adjuvant, and CTLA-4 blockade. Cancer Res. 2003 Jun 15;63(12):3281-8.
C19	DAVILA et al., Repeated administration of cytosine-phosphorothiolated guanine-containing oligonucleotides together with peptide/protein immunization results in enhanced CTL responses with anti-tumor activity. J Immunol. 2000 Jul 1;165(1):539-47.
C20	DAVIS et al., CpG ODN is safe and highly effective in humans as adjuvant to HBV vaccine: Preliminary results of Phase I trial with CpG ODN 7909. Third Annual Conference on Vaccine Res. 2000. Abstract s25, number 47.
C21	DE GRUJIL et al., Cancer vaccine strategies get bigger and better. Nat Med. 1999 Oct;5(10):1124-5.
C22	DONNELLY et al., Cancer vaccine targets leukemia. Nat Med. 2003 Nov;9(11):1354-6.
C23	EZZELL et al., Cancer "Vaccines": An idea whose time has come? J NIH Research. 1995;7:46-9.
C24	FILION et al., Development of immunomodulatory six base-length non-CpG motif oligonucleotides for cancer vaccination. Vaccine. 2004 Jun 23;22(19):2480-8.
C25	FORNI et al., Immunoprevention of cancer: is the time ripe? Cancer Res. 2000 May 15;60(10):2571-5.
C26	GALLICHAN et al., Intranasal immunization with CpG oligodeoxynucleotides as an adjuvant dramatically increases IgA and protection against herpes simplex virus-2 in the genital tract. J Immunol. 2001 Mar 1;166(5):3451-7.
C27	GAO et al., Bacterial DNA and lipopolysaccharide induce synergistic production of TNF-alpha through a post-transcriptional mechanism. J Immunol. 2001 Jun 1;166(11):6855-60.

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Sheet	6	of	9				

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